

Remarks

Amendments to the Specification

Objection to the Specification:

On page 2 of this paper the Applicant requests several amendments to the specification in response to the Examiner's objections.

In response to the Examiner's objection to the previous amendment of paragraph [0034], the Agent for the Applicant has deleted the word "inducible" and replaced the word "inducer" by the originally filed "lactose".

Despite complying with the Examiner's requested correction with respect to the addition of the term "inducible" to the term "expression", the Agent wishes to respectfully traverse the suggestion based upon the following. In the noted sentence, the phrase "with little or no induction" and the phrase "expression of the target protein is turned on automatically" clearly show that the expression being referred to in the opening phrase "growth pattern of expression" is inducible expression. Thus, in the view of the Applicant's Agent the addition of the qualifying term "inducible" to the term expression within the context of the entire sentence does not change the scope of the disclosure. The Agent has complied, however, because in the context of the entire sentence the word "inducible" can be considered redundant.

In response to the objection related to the "alteration to the Table 1" the Agent for the Applicant has repeated the request for this amendment and respectfully requests reconsideration and withdrawal of the objection. The mistake in the heading for Table 1 in the "as filed" paper is clearly understood by all who have a minimal level of skill in the

art and arts related to basic chemistry to be of a typographical nature. It is clear from basic chemistry that if the incorrectly typed notation " Na_2PO_4 " had been intended it would have been noted that this material has a net negative charge and would have been properly noted as " $\text{Na}_2\text{PO}_4^{-1}$ " since the ' PO_4 ' anion has a net charge of negative 3 (i.e., properly noted as PO_4^{-3}). In addition, one of basic skill in the art of buffer compositions would readily recognize that di-sodium phosphate in combination with either mono-sodium or mono-potassium phosphate are salts that are commonly used together to prepare a phosphate-buffered solution having a physiological pH range (for example, please see definitions of "phosphate buffered saline"). In the case at hand, if it had been the intention of the Applicant to make the notations in "ionic form" the mono-potassium phosphate would have been noted as " KPO_4^{-2} ".

Because the error was clearly of a typographical nature, the Agent respectfully requests withdrawal of the objection.

Amendments to the Claims

Rejection under 35 USC § 112, first paragraph:

The Examiner has maintained the written description rejection after finding the Applicant's previous arguments filed 11/6/06 unconvincing.

In response, the Applicant's request the Examiner's consideration of the following remarks and discussions.

Claims 1-22 and 40-52 have been cancelled, Claim 53 has been amended and new claims 54 – 60 have been added.

Claim 53 has been amended in an effort to advance the present case to a condition for allowance. The claim is drawn to the cells specifically described in the specification (see paragraph [0003], for example), i.e., the T7 expression system host strains. Further the *lac* and *lacUV5* promoters have been clearly described in the specification. In addition, the culture media of step a) of the method are precisely delineated in Table 1 of the specification. Furthering support for the claim as amended, it is clear from the specification that such T7 expression strains inoculated in such media, are merely grown to saturation to complete the auto-induction of transcription (and subsequent translation). See paragraph [0034] and following where the expression of “target protein P21” is described. See paragraph [0037] where saturation densities are discussed. See paragraph [0042] – “Both non-inducing and auto-inducing cultures are simply inoculated and grown to saturation.” And paragraph [0043] “. . . auto-inducing cultures are simply inoculated and grown to saturation”. Thus, the amendments of Claim 53 contain no new matter.

The Agent for the Applicant respectfully requests withdrawal of the rejection of Claim 53 and suggests that the claim is now in condition for allowance.

Consideration of newly added Claims 54 – 60:

In addition to the above remarks and reasoning with respect to the withdrawal of rejection of Claim 53, the Applicant’s Agent respectfully requests the Examiner’s consideration of newly added claims 54 through 60. The newly added claims are fully supported by the specification based upon reasoning similar to that put forth in support of amended Claim 53. T7 expression system host cells of independent claim 54 are

described in the specification and are known to those of skill in the art. The culture media of claim 54 are precisely described in Table 1 of the specification. And, the specification specifically states that auto-induction will occur by inoculating the media with the T7 host cells and growing them to saturation ("a saturating cell density").

The Applicant respectfully requests the Examiner's consideration that the new claims 55 through 60, which depend ultimately from the fully supported claim 54, are also in condition for allowance.

In closing, the Applicant submits that the present application is now in condition for allowance and respectfully anticipates receipt of a timely Notice of Allowance.

Respectfully Submitted,



Christine L. Brakel
Agent for the Applicant
Registration Number 45,772

Date: April 24, 2007

Christine L. Brakel
Patent Agent
Office of Intellectual Property and Sponsored Research
Brookhaven National Laboratory
Building 475D
Upton, New York 11973
Telephone: (631) 344-7134